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10/532,765

04/22/2005

Serge Louis Boulet

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PATENT DIVISION

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EXAMINER

SOLOLA, TAOFIQ A

ART UNIT

PAPER NUMBER

1625

NOTIFICATION DATE

DELIVERY MODE

09/28/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary

Application No.

10/532,765

Applicant(s)

BOULET ET AL.

Examiner

Taofig A. Solola

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-26 and 33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) 1-26, 33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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Claims 1-26, 33 are pending in this application.

Claims 27-32 are cancelled.

DETAILED ACTION

Election/Restriction

Claims 1-26, 33 are drawn to more than one inventive concept (as defined by PCT Rule 13) and, accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1(b), provides that "special technical features" mean those technical features which, as a whole, define a contribution over the prior art (novelty/unobviousness).

I. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is phenyl, Y is naphthypyridin-5-yl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

II. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is phenyl, Y is dihydrobenzothieryl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

III. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is phenyl, Y is benzoisothiazolyl or benzothiazolyl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IV. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is phenyl, Y is quinoline-5-yl or isoquinolin-5-yl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

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V. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is phenyl, Y is thienopyridinyl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VI. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is thienyl, Y is naphthypyridin-5-yl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VII. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is thienyl, Y is dihyrobenzothienyl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VIII. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is thienyl, Y is benzoisothiazolyl or benzothiazolyl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IX. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is thienyl, Y is quinoline-5-yl or isoquinolin-5-yl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

X. Claims 1-26, drawn to compounds of formula I and composition thereof, wherein X is thienyl, Y is thienopyridinyl, classifiable in several non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XI. Claim 33, drawn to methods of using compounds of groups I-X, classified in several heterocyclic classes (514, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

In the instant inventions, the only structural element shared by groups I-XI is $(CH)_2CH_2N$.

However, $(CH)_2CH_2N$ is obvious and/or not novel. Therefore, under PCT Rules 13.1 and 13.2, $(CH)_2CH_2N$ does not constitute a corresponding special technical feature among the groups.

If applicant elects any of the invention of groups I-X, one point of attachment of each ring X and Y must be specified and the elected group would be examined commensurate in scope therewith. Such point of attachment of each ring must be disclosed in the specification.

If applicant elects the invention of group XI, one of groups I-X and a specific disease must be selected. In a rejoinder applicant must select a specific disease. In either case, group XI would be examined commensurate in scope with the selected group and the specific disease.

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In an election of any of groups I-XI, a single compound (or set of compounds) an exact definition of each substitution on the base molecule (Formula I), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl, at each subsequent variable position.

In the instant case, Applicant must elect one representative for R1-R2, A, X Y, Z, etc, in formula I, and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic. Applicant must provide the structure of the species. The species must be disclosed in the specification. The parts of the elected species corresponding to the substituents in formula I must be identified.

In a telephone call made to Arive Anderson on 8/27/07, to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

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claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner before the patent issues withdraws the restriction requirement. See MPEP § 804.01.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.



**TAOFIQ SOLOLA
PRIMARY EXAMINER**

Group 1626